UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,640	12/01/2004	Robert E Click	Paralab I	6993

26365 7590 12/22/2010

Bourget Law
P.O. BOX 81
EAU CLAIRE, WI 54702-0081

EXAMINER	
MACAULEY, SHERIDAN R	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
12/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,640	CLICK, ROBERT E	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-29 and 31-54* is/are pending in the application.

4a) Of the above claim(s) *27-29,38,39,52 and 53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,31-37,40-51 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A response was received and entered on August 20, 2010. All evidence and arguments have been fully considered. New claims 45-54 have been added. Claims 1-25 and 30 are cancelled. Claims 26-29 and 31-54 are pending.

Election/Restrictions

1. Claims 27-29 are withdrawn due to a previous requirement for restriction.

2. Applicant's election of "a dose of bacterium" as the species of components of the composition in response to the supplemental requirement for restriction/election, which was mailed on July 21, 2010, is acknowledged. Applicant's reply was filed on August 20, 2010. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The reply is still deemed proper and is therefore made final.

3. Claims 27-29, 38, 39, 52 and 53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups and species, there being no allowable generic or linking claim.

4. Claims 26, 31-37, 40-51 and 54 are examined on the merits in this Office action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 26, 31-37, 40-51 and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a dose of an isolated bacterium of the *Dietzia* genus, wherein the bacterium is the strain deposited with accession number ATCC PTA-4125, such that the dose is capable of reducing or preventing the symptoms of a disease or syndrome whose causative agent is *Mycobacterium paratuberculosis*, does not reasonably provide enablement for a composition comprising a dose of an isolated bacterium of the *Dietzia* genus such that the dose is capable of reducing or preventing the symptoms of a disease or syndrome whose causative agent is a mycobacterium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

7. The claims recite a composition comprising a does having at least 10^9 cfu of an isolated bacterium of the genus Dietzia, such that the dose is capable of reducing or preventing the symptoms of a disease or syndrome whose causative agent is a mycobacterium. The claims further recite compositions comprising a bacterium of the *Dietzia* genus, wherein the bacterium is the strain deposited with accession number ATCC PTA-4125. The claims further recite that the compositions further comprise animal feeds and feed additives, that that the composition is formulated into various dosage forms, that the dose comprises 10^9 to 10^{14} cfu, at least 10^{10}, 10^{11}, 10^{12}, 10^{13} or 10^{14} cfu of the bacterium, and that the dose is formulated for administration to an animal or mammal.

8. In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the instant case, those factors deemed most relevant are the amount of direction and guidance presented, the presence or absence of working examples, and the nature of the invention.

9. The disclosure is not enabling for composition comprising a dose of an isolated bacterium of the *Dietzia* genus such that the dose is capable of reducing or preventing the symptoms of a disease or syndrome whose causative agent is a mycobacterium because it does not present enough direction an guidance for one skilled in the art to use the invention with a reasonable expectation of success without undue experimentation. The disclosure does not provide any guidance or working examples to direct one to use the invention with a strain other than the strain of *Dietzia* deposited with accession number ATCC PTA-4125 or to treat a disease wherein the causative agent is a mycobacterium other than *Mycobacterium paratuberculosis*. The working examples disclosed in the instant application are directed to the treatment of Johne's

disease in cattle using the strain of *Dietzia* deposited with accession number ATCC PTA-4125. There are no working examples that would give one of ordinary skill in the art a reasonable expectation of success in using a different strain of *Dietzia* from the one discussed in the examples of the specification in treating this disorder. Also, the disclosure does not provide a reasonable expectation of success in treating any disease other than Johne's disease wherein the causative agent is a mycobacterium. Further, the state of the prior art indicates that the treatment of Crohn's disease, which is disclosed in the specification as related to Johne's disease and treatable using the claimed invention, is poorly understood. Kruis et al. (Ailmentary Pharmacology and Therapeutics, 2004, 20:75-78) teaches that it is unclear whether a mycobacterium is in fact the casuative agent for treating Crohn's disease, and further discusses that treatments targeting mycobacteria were not predictably effective In treating the disorder (p. 76, col. 2). Thus, one of ordinary skill in the art would conclude that the mechanisms by which such disorders are treated are complex and that a treatment regimen for one disorder cannot be directly extrapolated from a treatment regimen for the other. Given these facts, one skilled in the art would be unable to predict whether the claimed composition could be used as described in the claims with a reasonable expectation of success.

10. Therefore, the disclosure of the instant application does not enable one skilled in the art to use the invention as claimed.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 31, 42, 44, 51 and 54 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. According to the disclosure of the instant application, the strain of *Dietzia* recited in claims 31, 42 and 44 was isolated from a natural source, specifically feces (see specification, p. 12, par. 36). Claims 51 and 54 also read on this strain of the bacterium. Further, claims 51 and 54 recite a composition comprising a bacterium of the genus *Dietzia*. Bacteria of the genus recited in the claims are found in nature, i.e. in natural compositions, as evidenced by Duckworth et al. (Extremophiles, 1998, 2:359-366; document cited in IDS), who teach a strain of *Dietzia* found in a natural soda lake. The claims do not recite that the organism in the composition is isolated or in some way separate from the natural environment. Therefore, the claims read on a product of nature and are thus directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

13. Rejections under 35 USC 102 have been withdrawn due to applicant's amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 26, 32-37, 40, 45-51 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkemade et al. (US 6,139,844; document cited in previous action) in view of Mosser (WO 99/05304; document cited in previous action) and Rainey et al. (International Journal of Systematic Bacteriology, 1995, 45:32-36; document cited in IDS).

4. The claims recite a composition comprising a does having at least 10^9 cfu of an isolated bacterium of the genus *Dietzia*, such that the dose is capable of reducing or preventing the symptoms of a disease or syndrome whose causative agent is a mycobacterium. claims further recite that the compositions further comprises an animal feed comprising various components and a feed additive, such as a vitamin, mineral,

protein supplement or drug, that the composition is incorporated into a dosage form such as a tablet comprising various components, that the dose comprises 10^9 to 10^{14} cfu, at least 10^{10}, 10^{11}, 10^{12}, 10^{13} or 10^{14} cfu of the bacterium, and that the dose is formulated for administration to an animal or mammal.

5. Alkemade teaches the compositions comprising components of bacteria of the Actinomycetales, such as *Rhodococcus* or *Nocardia*, for administration to animals (col. 2, lines 36-60). Alkemade teaches that such compositions may be prepared in various formulations, such as a tablet that contains a base (e.g., powder), disintegrator (e.g. dispersing agent), absorbent, binder and lubricant (col. 6, line 54-col. 7, line 5). The reference teaches that the compositions may be formulated for oral administration, such as in a lozenge, which would comprise an edible product such as those recited in the claims and a mineral such as a salt (col. 7, lines 6-31). The reference does not specifically teach the use of a species of the genus *Dietzia*.

6. Mosser teaches the preparation of strains of *Rhodococcus* for use in eliciting an immune response, such as an active *Rhodococcus* cell (abstract, p. 8, lines 4-14; p. 12, lines 10-21).

7. Rainey teaches that members of the genus *Dietzia* are closely related to *Rhodococcus* and were once considered to be in the same genus (p. 359).

8. At the time of the invention, bacteria of the Actinomycetales, such as *Rhodococcus*, were known to be useful in compositions for the administration to animals, as taught by Alkemade and Mosser. At the time of the invention, species of the genus *Dietzia* were known to be closely related to and previously considered to be of

the same genus as *Rhodococcus*. Although none of the references specifically teach compositions comprising bacteria of the genus *Dietzia*, Alkemade and Mosser teach that one would have a reasonable expectation of success in selecting any species of *Rhodococcus* or related organisms for the preparation of compositions such as those recited in the claims. One would therefore have been able to choose from the finite number of identified, predictable species of bacteria for the preparation of such compositions, *Rhodococcus maris* (i.e. *Dietzia maris*) being one of them. One would therefore have been motivated to practice and would have had a reasonable expectation of success in practicing the claimed invention. Furthermore, the selection of a dosage such as those recited in the claims would have been a matter of routine experimentation by one of ordinary skill in the art, particularly because the ranges recited in the claims are broad, as is the method by which the dosage is to be administered; thus, one of ordinary skill in the art could have arrived at a dosage that meets the claim limitations in the course of routine experimentation. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

9. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

10. Applicant's arguments filed May 14, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are patentable under 35 USC 101

because the claims have been amended to recite an isolated bacterium. However, this limitation is not recited in all of the claims, as is discussed in the rejections above. Therefore, applicant has not overcome all of the rejections under 35 USC 101 by amendment. Applicant also argues that the rejections under 35 USC 103 have been overcome by applicant's amendment to the claims, which now recite that the bacterium recited in the claims is administered at a specific amount of cfu per dose. However, the selection of a dosage such as those recited in the claims would have been a matter of routine experimentation by one of ordinary skill in the art, particularly because the ranges recited in the claims are broad, as is the method by which the dosage is to be administered; thus, one of ordinary skill in the art could have arrived at a dosage that meets the claim limitations in the course of routine experimentation, as discussed in the rejections above. Although applicant further argues that the compositions have the surprising benefit recited in the claims, i.e., the reduction or prevention of the symptoms of a disease or syndrome whose causative agent is mycobacterium, the evidence provided by applicant in the specification is not commensurate in scope with the claims. Applicant's evidence only shows that the strain deposited under the accession number ATCC PTA-4125 may be used for the treatment or prevention of Johne's disease in cattle. As discussed in the rejections made under 35 USC 112 above, this evidence does not provide enablement for the full scope of the claimed invention, and thus is not commensurate in scope with the claims so as to provide evidence of unexpected results. Therefore, applicant's argument has not been found to be persuasive.

11. Thus, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651